Clinical Trial Details (PDF Generation Date :- Thu, 29 Oct 2020 06:19:28 GMT)

CTRI Number	CTRI/2020/04/024479 [Registered on: 07/04/2020] - **Trial Registered Prospectively**
Last Modified On	31/08/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Study of the effect of Hydroxychloroquine in addition to standard therapy in COVID-19 patients
Scientific Title of Study	Open labelled Randomised controlled trial to study the effect of Hydroxychloroquine in addition to standard therapy in COVID-19 patients

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	SALIL GUPTA
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Source of Monetary or Material Support

Source of Monetary or Material Support
> COMMAND HOSPITAL AIRFORCE BANGALORE

Primary Sponsor

Primary Sponsor Details	
Name	COMMAND HOSPITAL AIRFORCE
Address	AGRAM POST BANGALORE PIN 560007
Type of Sponsor	Other [INDIAN AIRFORCE HOSPITAL]

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
SALIL GUPTA	COMMAND HOSPITAL AIRFORCE	AGRAM POST BENGALURU 560007 Bangalore KARNATAKA	8197751281 chickusalil@yahoo.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
INSTITUTIONAL ETHICS COMMITEE COMMAND HOSPITAL AIRFORCE	Approved	31/03/2020	No
INSTITUTIONAL ETHICS COMMITEE COMMAND HOSPITAL AIRFORCE	Approved	12/08/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Coronavirus as the cause of diseases classified elsewhere

Intervention / Comparator Agent

Type	Name	Details
Intervention	Hydroxychloroquine sulphate	Hydroxychloroquine sulphate tablets will be given in the dose of 400 mg twice on day 1 and then 400 mg once in a day for 04 days daily to the patients who meets the inclusion criteria
Comparator Agent	No drug	Hydroxychloroquine will not be given to control group. These patients will be managed as per standard protocol.

Inclusion Criteria

Inclusion Criteria	
Age From	14.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	a. Patients with oxygen saturation (SPO2) less than 95% b. Respiratory rate is more than 20/min

	c. Pulse rate more than 90/min d. Imaging evidence of lung infection in the form of Reticulonodular opacities, ground-glass opacities, consolidation and Acute Respiratory Distress Syndrome (ARDS)

Exclusion Criteria

Exclusion Criteria	
Details	a. Asymptomatic patients b. Patients with mild illness (not satisfying inclusion criteria) c. Patients allergic to chloroquine d. Patients less than 14 years of age e. Patients unwilling for informed consent f. Pateints with prolonged QTc interval on ECG

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	An Open list of random numbers
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
number of days of hospitalization	discharge

Secondary Outcome

Outcome	Timepoints
death days to normalization of SaO2 days to normalization of pulse rate less than 90/min number of days of requirement of oxygen number of days from admission to ventilator requirement number of days on ventilator and occurrence of side effects	death or discharge

Target Sample Size	**Total Sample Size=**32 **Sample Size from India=**32 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	N/A
Date of First Enrollment (India)	13/04/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	will be published in indexed medical journal
Brief Summary	In December 2019, an outbreak of an emerging disease (COVID-19) due to a novel coronavirus (named SARS-CoV-2 later) started in Wuhan, China, and rapidly spread in China and outside. The disease rapidly spread to European countries and American countries. India also started reporting cases of COVID 19 from various states. The etiologic agent responsible for the present outbreak of COVID 19 is a novel Coronavirus, closely related to the SARS-Corona virus, and has been named as SARS-CoV-2. Hydroxychloroquine/Chloroquine has been demonstrated to have an anti- SARS-CoV 2 activity in vitro. In one open-labeled non-randomized French study, chloroquine/Hydroxychloroquine has shown a significant reduction in viral load compares to the control group. The aim of the study is to determine whether Hydroxychloroquine is beneficial in COVID-19 patients who present with Severe Acute Respiratory Illness (SARI). In our study, we propose to determine the effectiveness of hydroxychloroquine in reducing the number of days of hospitalization in intervention as opposed to the control group. It will be an open-labeled randomized controlled trial. A total of 32 patients (16 in each group) will be taken into the study. Sample size calculation has been done using online calculator ClinCalc.com assuming the primary endpoint being the number of days of hospitalization. Assuming an average patient of COVID-19 infection with SARI will stay in the hospital for a mean of 15±5 days the intervention will be considered significant if the intervention reduces the number of days by a one third i.e. a mean of 10 days. The alpha error is 0.05 and the power of the study is 80%. The study will be conducted in this hospital on patients who are detected to be COVID 19 positive based on Reverse Transcription Polymerase Chain Reaction (RT PCR). All the patients meeting inclusion criteria will be enrolled in the study. Computer-generated randomization will be done to enroll patients in the intervention group and control group respectively after taking consent. Those in the intervention group will receive chloroquine 500 mg two times per day for 10 days. The patients in the control group will not receive hydroxychloroquine. The project has significant scope to add to the existing repertoire of understanding about the management of COVID-19. It will tell us about the effectiveness of hydroxychloroquine in the treatment of COVID-19